9. 510 (k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device.

Qualis Claims substantial equivalence to K-Y Ultra Gel Personal Lubricant (K020827), currently in commercial distribution by Personal Products Company Division of McNeil-PPC inc..

B. Device Description.

Personal Lubricating Gel is a non-sterile, clear, non-staining, non-greasy, liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity.

C. Intended Use.

Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.

D. Comparison with Predicate Device.

A summary comparison of the features of Lubricating Gel and the Predicate Device K-Y Brand Ultra Gel Personal Lubricant is provided in Table 1.

E. Performance Data

Non-Clinical Studies.

1. Stability.

Personal Lubricating Gel has successfully passed 90 day accelerated stability.

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2. Preservative Effectiveness.

An anti-microbial preservative challenge has been completed for Personal Lubricating Gel. The Preservative Effectiveness Study Report is in Attachment E.

3. Comparison with Predicate Device.

Personal Lubricating Gel was compared to K-Y Brand Ultra Gel Personal Lubricant on the basis of perceptual qualities, physical and chemical properties, ingredients list review, label claims, and packaging. The result of this review was an acceptable comparison. See Attachment B for the ACTS comparison Report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

Mr. Mike Peterson
Quality Assurance Manager
Qualis, Inc.
4600 Park Avenue
DES MOINES IA 50321

Re: K041129
Trade/Device Name: Personal Lubricating Gel
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): August 26, 2004
Received (Date on orig SE ltr): August 26, 2004

Dear Mr. Peterson:

This letter corrects our substantially equivalent letter of September 24, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041129

Device Name: Personal Lubricating Gel

Indications For Use: Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms

Prescription Use _____ ~~AND~~/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041129